**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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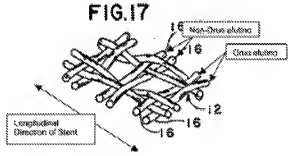
| Applicant: | Harder et al. | Examiner: | Suba Ganesan |
| Ser. No.: | 10/562,376 | Art Group: | 3738 |
| Title: | STENT COMPRISING A COATING SYSTEM | | |
| Filed: | 23 December 2005 | Date: | 4 February 2008 |

**PRE-APPEAL BRIEF REQUEST FOR REVIEW AND STATEMENT ACCOMPANYING REQUEST FOR PRE-APPEAL BRIEF REVIEW**

A pre-appeal brief request for review is hereby made. The Applicants maintain that the Examiner has not established prima facie cases of anticipation of claims 1-3 and 9-11, or of obviousness of pending claims 4-5.

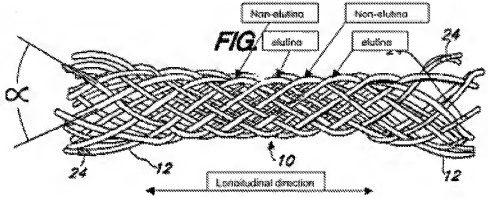
The Examiner rejected claims 1-3 under 35 U.S.C. § 102(b) as anticipated by Wolff (WO 91/12779), and claims 9-11 under 35 U.S.C. § 102(e) as anticipated by Sirhan et al. (US 2003/0083646). Claims 4-5 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Wolff in view of Sirhan et al.

To anticipate a claim, a reference must teach all elements of the claim (MPEP § 2131). The Examiner maintains that Wolff provides a stent with a polymer carrier and a pharmaceutically active substance, the concentration of which varies in the longitudinal direction of the stent. To support this contention, the Examiner provided an annotated copy of Fig. 17 of Wolff, reproduced below:

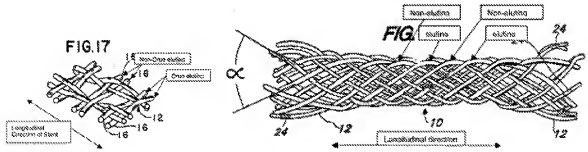



The Examiner provides examples of filaments that are either drug-eluting or non-drug eluting with reference to Fig. 17. The Examiner also assigns a longitudinal direction of the stent and

maintains that with such an orientation, there would be a variation in drug eluting and non-eluting characteristics in the longitudinal direction. However, Wolff is silent on the longitudinal direction relative to Fig. 17. One of ordinary skill in the art, considering the teachings of Wolff as a whole, would look to other sections of Wolff for the orientation of the stent. Fig. 1 of Wolff implicitly provides a longitudinal direction by providing a drawing of an entire stent. No other orientation is provided by Wolff.




Comparing the Examiner's annotated versions of Figs 1 and 17 side-by-side, it becomes clear that in annotated Fig. 17, the Examiner has selected a longitudinal direction that actually corresponds more closely to the upper or lower arm forming angle α, than to the actual longitudinal axis, shown by the Examiner in annotated Fig. 1. The longitudinal orientation provided by the Examiner in annotated Fig. 17 is clearly skewed from the orientation of the woven structure provided by Wolff in Fig. 1 as annotated by the Examiner.




Additionally, if the Examiner's assigned orientation in Fig. 17 were applied to an entire stent, the result would be a succession of rings of drug-eluting and non-drug eluting strands woven with strands extending the entire longitudinal length of the stent. No provision

is made by the Examiner for securing the ends of each of such "ring" strands. Therefore, in assigning the longitudinal direction provided in annotated Fig. 17, the Examiner is actually modifying the teachings of Wolff in an attempt to establish anticipation of the present invention.

The Examiner also states:

> "Wolff further provides for varied elution that occurs along the longitudinal direction with parallel longitudinal fibers that are eluting and non-eluting. The overall structure of Wolff is woven (as seen in annotated fig. 1). Alternating eluting and non eluting fibers provide a variance in the longitudinal direction such that the pharmaceutically active substance exhibits predetermined locally different elution characteristic when a longitudinal cut is made through the stent. Therefore parallel *longitudinal* fibers (still) exhibit a variance in the longitudinal direction of the stent."

It is unclear to the Applicants how the Examiner can state, "Alternating eluting and non eluting fibers provide a variance in the longitudinal direction..." Although it may be difficult to follow an individual strand in Fig. 1 continuously from its beginning to end, Fig. 1 clearly shows that the drug-eluting and non-eluting strands are present along the entire length of stent 10. Termini of individual strands are only shown at each end of Wolff's stent. Furthermore, the weave appears to be entirely symmetric along the entire length of the stent. Therefore, the presence of drug-eluting and non-eluting strands is constant over the length of the stent provided by Wolff in Fig. 1.

Additionally, even assuming, *arguendo*, that the Examiner is correct in stating that Wolff's stent provides "locally different elution characteristics," the claims recite more than just the resulting elution characteristics of the stent. Claim 1 also recites a varying *concentration* in the stent along the longitudinal direction, in addition to a differing elution characteristics. As provided above, the entirely symmetrical weave of drug eluting and non-

eluting strands in Wolff provides no variation in concentration along the longitudinal direction.

Because Wolff provides no teaching or suggestion for varying the concentration of a pharmaceutically active substance along the longitudinal direction of the stent as recited in claim 1, it and claims 2-5, which depend from and include all the limitations of claim 1, patentably distinguish over Wolff. Reversal of the Examiner's rejection of claims 1-3 under U.S.C. § 102(b) as anticipated by Wolff is respectfully requested.

Claims 9-11 stand rejected under 35 U.S.C. § 102(e) as anticipated by Sirhan et al. The Examiner maintains that Sirhan et al provide a stent as recited in claim 9. The Examiner maintains that the use of a co-polymer constitutes a material modification of the at least one carrier by providing varying degradation rates over the length of the stent. However, such an interpretation ignores that claim 9 separately recites the presence of one or more polymer carriers. Sirhan only provides a mixture of polymers, not a modification of those polymers. By reading the presence of one or more polymers into two distinct limitations of claim 9, the Examiner has not provided a single reference that teaches all the limitations of claim 9. Therefore, claim 9, and claims 10-11 which depend from and include all the limitations of claim 9 patentably distinguish over Sirhan et al. Reversal of the Examiner's rejection of claims 9-11 under U.S.C. § 102(e) as anticipated by Sirhan et al. is respectfully requested.

The Examiner maintains that under 35 U.S.C. § 103(a), claims 4-5 are unpatentable over Wolff in view of Sirhan et al. The distinctions between the present invention as claimed and those of Wolff and Sirhan are provided above and are repeated with regard to the rejection under 35 U.S.C. § 103(a). Additionally, the Examiner maintains "It would have been obvious to one of ordinary skill in the art to locate the drug eluting fibers of Wolff toward the end (near the face surfaces) using motivation derived from Sirhan, the motivation being: providing different drug elution characteristics near the face surfaces of the stent (para.34)." However, as provided above, Wolff does not provide a variation in the concentration of a pharmaceutical agent along the longitudinal direction. Therefore, one of ordinary skill in the art would have found no teaching or suggestion in Wolff to locate drug-

eluting fibers only toward the ends of the stent as alleged by the Examiner and the Examiner has not established a *prima facie* case of obviousness of claims 4-5. Reversal of the Examiner's rejection of claims 4-5 under U.S.C. § 103(a) as obvious over Wolff in view of Sirhan et al. is respectfully requested.

The final Office Action was mailed on 2 November 2007. No extension of time or accompanying fee is believed to be due in making this response because February 2, 2008 fell on a Saturday and this response is timely filed on the next business day, February 4, 2008. However, in the event that the need for a petition for an extension of time has been overlooked, a conditional petition for the necessary extension of time is hereby made with this Notice of Appeal and Request for Pre-appeal Brief Review. The Commissioner is authorized to charge any fee required with the filing of this response or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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